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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,734	07/13/2001	Yoshikatsu Kodama	011900-310	9324

7590 11/19/2003

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/19/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/903,734

**Applicant(s)**

KODAMA ET AL.

**Examiner**

Vickie Kim

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Status of application***

1. The application was withdrawn from issue(see paper no. 13). There are some issues that are needed to be address before the issuance. The claims 1-4 and 7-8 are currently pending and presented for the examination.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the claim 3, line 7, the phrase “,wherein said IgY antibodies are capable of specifically binding to the adhesion portion of *helicobacter pylori* urease” was deleted from original claim 3(right before “in the gastrointestinal”) when it is reproduced and thus, this reproduced claim is confusing. However, it seems to be an inadvertent clerical error because it is readily apparent because applicant amended without marking up to show this change(37 CFR 1.121). Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama(US 6,419,926) in view of Kodama(EP1010434).

Claims are directed to a composition consisting essentially of IgY antibodies and at least one agent selected from H2 blockers and proton pump inhibitors, wherein the said composition is used to treat gastric ulcers via inhibiting Helicobacter Pylori(Hp) colonization. Kodama(US'926 hereafter) teaches a composition containing anti-urease antibodies in combination with secondary beneficial additives such as antacids, digestive enzymes and so on, see column 7, lines 10-21. US'926 further teaches a combination of anti-urease antibodies and lactic acid bacterium that shows synergism, see column 6.

Applicants claims differ because they require at least one of H2 blockers or proton pump inhibitors.

However, it would have been obvious to one of ordinary skill in the art to substitute the secondary additive(e.g. antacids, digestive enzymes or lactic acid bacterium) with H2 blockers or proton pump inhibitors at the time of the invention was made when US'926 is taken in view of EP'434 because EP'434 teaches H2 blockers or proton pump inhibitors as beneficial additives that can improve the therapeutic efficacy of helicobacter pylori inhibitor composition.

EP'434 also teaches other beneficial additives such as antacids, digestive enzymes, etc. EP'434 further teaches the synergistic effects of inhibitory activity against HP colonization when a primary active agent(i.e. mucin) is combined with H2 blockers or proton pump inhibitors.

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EP'434 teaches helicobacter pylori colonization inhibitor composition containing mucin as an active agent in combination with various beneficial additives such as H2 inhibitors, proton pump inhibitors, antacids, etc, see page 4, lines 45-59. EP'434 further teaches synergism achieved by adding H2 inhibitor or proton pump inhibitors.

One would have been motivated to make such substitution, with reasonable expectation of success when the teaching of these references are coupled with the conventional knowledge and information available in the art because the substitution would improve the therapeutic effectiveness but reduce side effects associated with drug regimen. It is readily apparent to any skilled artisan because H2 blockers and proton pump inhibitors are well known drug used for treating gastric ulcer. It is also conventionally known to artisan having ordinary skill in the art that H2 blockers or proton pump inhibitors are known to be newer generation drugs which are superior compared to old generation drugs(e.g. antacids, digestive enzymes) due to their potent inhibitory activity against acid secretion and the reduced side effect.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

### ***Conclusion***

6. No claim is allowed.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,  
Primary Patent Examiner  
Art unit 1614